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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/031,008 | 05/06/2002 | Steven K Libutti | 14014.0322U2 | 3848 |

36339 7590 09/23/2005

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| EXAMINER | |
|---|---|
| BURKHART, MICHAEL D | |
| **ART UNIT** | **PAPER NUMBER** |
| 1633 | |

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 10/031,008 | LIBUTTI ET AL. |
| | Examiner | Art Unit |
| | Michael D. Burkhart | 1633 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-22 drawn to a compound comprising a nucleic acid encoding an antiangiogenic protein inserted within a viral nucleic acid, and viruses comprising the compound.

Group II, claim(s) 23-28, and 31, drawn to methods of delivering or producing an antiangiogenic protein in a cell, comprising administering the virus of Group I to a cell.

Group III, claim(s) 29-30, drawn to methods of delivering an antiangiogenic protein to a subject or treating a tumor in a subject, comprising administering the virus of Group I to a subject. (Note, claim 29 specifies "the adenovirus of claim 3", but claim 3 is a retrovirus)

Group IV, claim(s) 32-36, drawn to methods of screening an antiangiogenic protein for bioactivity using the compounds of Group I.

Group V, claim(s) 37-39, drawn to a protein comprising an antiangiogenic protein and a signal sequence.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking Groups I-IV is a compound comprising a nucleic acid encoding an antiangiogenic protein inserted within a viral nucleic acid. However, Tanaka et al (Nat. Medicine, 1997, cited by applicants in the IDS of 10/15/2002) disclose retroviral and adenoviral vectors which contain nucleic acids encoding the antiangiogenic protein platelet factor 4. See the abstract and Fig. 1, page 438.

Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. Group V is directed to a protein comprising an antiangiogenic protein and a signal sequence, not shared by the other Groups. All the other groups are directed to nucleic acids and viral vectors comprising the nucleic acids, a feature not found in Group V.

The technical feature of Group I is considered to be a compound comprising a nucleic acid encoding an antiangiogenic protein inserted within a viral nucleic acid.

The technical feature of Group II is considered to be administering the virus of Group I to a cell.

The technical feature of Group III is considered to be administering the virus of Group I to a subject.

The technical feature of Group IV is considered to be using the compounds of Group I in a bioactivity screening assay.

The special technical feature of Group V is considered to be a protein comprising an antiangiogenic protein and a signal sequence.

Accordingly, Groups I-V are not so linked by the same concept or a corresponding technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

In Group I, species I, an adenovirus nucleic acid or a retroviral nucleic acid;

In Group I, species II, the antiangiogenic proteins of claims 4-15;

In Group II, species I, administration of an adenovirus or retrovirus;

In Group II, species II, administration *ex vivo*, *in vivo*, or *in culture*;

In Group III, administration of an adenovirus or retrovirus.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Group I, species I, claims 2, 3, 16-19;
Group I, species II, claims 4-15;
Group II, species I, claims 23-28 and 31;
Group II, species II, claims 24-26;
Group III, claim 30

The following claim(s) are generic: 1, 23, 30.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: as explained above, the adenovirus and retrovirus nucleic acids and vectors, and the antiangiogenic protein platelet factor 4 (claim 12) are anticipated by Tanaka et al and therefore lack unity of invention. All of the antiangiogenic proteins listed in claims 4-15 have a different amino acid sequence and therefore have different structures and special technical features. The methods of Group II, species II all differ in the necessary route of administration (i.e., in vivo, in culture) and outcome, and therefore have different special technical features.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael D. Burkhart
Examiner
Art Unit 1633

CELIAN QIAN
PATENT EXAMINER